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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
LAM, ANN Y	

ART UNIT	PAPER NUMBER
1641	

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03/13/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/835,298	DAHLEN ET AL.	
	Examiner	Art Unit	
	ANN Y. LAM	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10/30/06 (after Board review)*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23-38* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *23-26,29-32 and 35-38* is/are allowed.

6)☒ Claim(s) *27,28,33 and 34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

It is noted that the species election requirements in the Office action of March 24, 2006 are hereby withdrawn, as all the species are found to be allowable (see below under "Allowable Subject Matter"). Therefore, claims 29-31 and 35-37 (previously indicated as withdrawn) are hereby rejoined.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 27, 28, 33, 34 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants reasonably provide guidance in the specification for a method for predicting cardiac mortality rate or a method of assigning a prognosis of subsequent myocardial infarction, or subsequent onset of angina, or subsequent onset of congestive heart failure, or subsequent death, by performing an assay for the markers: 1) BNP or

NT-proBNP or pro-BNP, and 2) cardiac Troponin-T or cardiac Troponin-I or CK-MB or C-reactive protein. However, the rejected claims recite in general a method of assigning a prognosis to a patient with or diagnosed with acute coronary syndrome, and relating the binding of the markers to the prognosis, without specifying the particular type of prognosis. Moreover, Applicants do not provide written description or guidance to other types of prognoses that can be made with the detection of the combination of these markers. As Applicants state on page 5 of the specification, the term "prognosis" refers to an increased probability that a certain course or outcome will occur. Thus, by generally claiming a method of assigning a prognosis to a patient with or diagnosed with acute coronary syndrome, the claims encompass numerous possible prognoses (i.e., increased probability of any of various certain course or outcome); however, only a few are actually described in the specification, namely, cardiac mortality, subsequent myocardial infarction, subsequent onset of angina, subsequent onset of congestive heart failure or subsequent death. Accordingly, the specification does not provide adequate written description of the general method as recited in claims 27, 28, 33, 34.

Claims 27, 28, 33, 34 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the method as it relates to a method for predicting cardiac mortality rate or a method of assigning a prognosis of subsequent myocardial infarction, or subsequent onset of angina, or subsequent onset of congestive heart failure, or subsequent death, does not reasonably provide enablement for the method as it relates to a method of assigning a prognosis, in general. The specification

does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The nature of the invention:

The invention is directed toward assigning a prognosis to a patient with or diagnosed with acute coronary syndrome. It is noted that Applicants state on page 5 of the specification, the term "prognosis" refers to an increased probability that a certain course or outcome will occur. Thus, the term "prognosis" can relate to *any* course or outcome.

The predictability or lack thereof of in the art:

It is not predictable that the markers will allow for assigning a prognosis other than those disclosed by Applicants, as biological pathways and mechanisms are complex and thus a correlation between a biological molecule to likelihood of a course or outcome (e.g., a medical condition) cannot be easily or readily determined.

The amount of direction or guidance present:

There is a lack of direction or guidance in the art as well as in Applicants' own specification regarding other types of prognoses that can be assigned from the detection of these markers.

The presence or absence of working examples:

It is acknowledged that Applicants reasonably provide guidance for a method for predicting cardiac mortality rate or a method of assigning a prognosis of subsequent myocardial infarction, or subsequent onset of angina, or subsequent onset of congestive heart failure, or subsequent death, by performing an assay for the markers: 1) BNP or NT-proBNP or pro-BNP, and 2) cardiac Troponin-T or cardiac Troponin-I or CK-MB or C-reactive protein. However, the rejected claims recite in general a method of assigning a prognosis to a patient with or diagnosed with acute coronary syndrome, and relating the binding of the markers to the prognosis, without specifying the particular type of prognosis. Applicants do not provide written description or guidance for other prognoses that can be made with the detection of these markers.

The quantity of experimentation necessary:

As Applicants state on page 5 of the specification, the term "prognosis" refers to an increased probability that a certain course or outcome will occur. Thus, by generally claiming a method of assigning a prognosis to a patient with or diagnosed with acute coronary syndrome, the claims encompass numerous possible prognoses (i.e., increased probability of any of various certain course or outcome); however, only a few are actually described in the specification, namely, cardiac mortality, subsequent myocardial infarction, subsequent onset of angina, subsequent onset of congestive

heart failure or subsequent death. It is not clear, and is unpredictable absent further experimentation, that the combination of the above markers can be used to assign prognoses that are not described in the specification. Note that an enabling disclosure for a method of assigning prognoses of a few particular types does not enable all possible prognoses.

The relative skill of those in the art:

The level of skill in the art is high. However, it is noted that a patent is granted for a completed invention, not the general suggestion of an idea and how that idea might be developed into the claimed invention. In the decision of *Genentech Inc. v. Novo Nordisk*, 42 USPQ 2d 1001 (CAFC 1997), the court held that: "[p]atent protection is granted in return for an enabling disclosure of an invention, not for vague intimations of general ideas that may or may not be workable" and that "[t]ossing out the mere germ of an idea does not constitute enabling disclosure." The court further stated that: "when there is no disclosure of any specific starting material or of any of the conditions under which a process is to be carried out, undue experimentation is required; there is a failure to meet the enablement requirements that cannot be rectified by asserting that all the disclosure related to the process is within the skill of the art", "[i]t is the specification, not the knowledge of one skilled in the art, that must supply the novel aspects of an invention in order to constitute adequate enablement."

The breadth of the claims:

The rejected claims recite in general a method of assigning a prognosis to a patient with or diagnosed with acute coronary syndrome, without specifying the

particular type of prognosis. The rejected claims thus encompass numerous possible prognoses (i.e., increased probability of any of various certain course or outcome). Again, it is not clear, and is unpredictable absent further experimentation, that the above markers can be used to assign prognoses that are not described in the specification.

In summary, there is a lack of disclosure in the art as well as in Applicants' own specification regarding a correlation between the detection of the recited markers and any or all types of prognoses in patients with or diagnosed with acute coronary syndromes. While Applicants reasonably provide guidance for certain specific prognoses disclosed in the specification, Applicants do not provide written description or guidance for other types of prognoses that can be made with the detection of these markers, and the skilled artisan, without undue experimentation, cannot predict what other types of prognoses can be made with the detection of these markers. It is emphasized that an enabling disclosure for a method of assigning prognoses of a few particular types does not enable all possible prognoses. Thus, the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these rejected claims.

It is also noted that while the present claims have been before the Board of Patent Appeals and Interferences, the Board only reviews the issues presented to the Board, and the present issues regarding written description and enablement were *not* presented to the Board. The Board's decision has been taken into consideration in

indicating the allowable subject matter below. However, upon reconsideration of claims 27, 28, 33, 34, the above rejections were found to be appropriate.

Allowable Subject Matter

Claims 23-26, 29-32, 35-38 are allowed.

The following is an examiner's statement of reasons for allowance. The prior art does not teach a method of predicting cardiac mortality rate or of assigning a prognosis of subsequent myocardial infarction, subsequent onset of angina, subsequent onset of congestive heart failure or subsequent death, by detecting the combination of markers: 1) BNP or NT-proBNP or proBNP and 2) cardiac Troponin-T or cardiac Troponin-I or CK-MB or C-reactive protein. Nor does the prior art suggest that it would have been expected that detection of such a combination of markers would provide improvement in the accuracy of such prediction or prognoses than from measuring either marker alone.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANN Y. LAM whose telephone number is (571)272-0822. The examiner can normally be reached on Mon.-Fri. 10-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mark Shibuya can be reached on 571-272-0806. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Ann Y. Lam/
Primary Examiner, Art Unit 1641